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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,688	05/14/2001	David N. Cooper	WCM78	6577

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,688	Applicant(s) COOPER ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,30-41 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28, 30-41, 44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the "Use" claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. Claims 40, 41 and 44 appear to be inclusive of methods of using a medicant comprising a GH1 variant nucleic acid, methods of detecting a GH1 variant using a GH1 variant nucleic acid, and kits comprising a GH1 variant nucleic acid. These are distinct methods and compositions. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups. Furthermore, it is noted that it has been interpreted that claims 12-16, 28, 30-31, 34-37 and 44 are limited to GH1 **nucleic acids** and do not include proteins (since the variants are defined in the dependent claims as encoding for a protein).

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, 21-27, 40 and 41, drawn to methods for detecting variations in the nucleic acids of GH1, classified in Class 435, subclass 6.

II. Claims 12-16, 28, 30-31, 34-37, and 44, drawn to GH1 nucleic acid variants, vectors containing a GH1 nucleic acid variant, and methods of culturing a host cell to obtain a GH1 nucleic acid variant, classified in Class 536, subclass 23.5 and Class 435, subclass 320.1.

III. Claims 17-20, 38 and 39, drawn to GH1 variant proteins, classified in Class 530, subclass 350.

IV. Claims 32-33, drawn to methods to detect GH1 variant proteins, classified in Class 435, subclass 7.1.

V. Claims 40, 41 and 44, drawn to a method of treatment comprising administering a GH1 variant nucleic acid, classified in Class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention III are not required to practice the method of invention I.

Inventions I, IV and V are drawn to patentably distinct methods, which require performing different method steps, involve the use of different reagents and/or have different objectives. In particular, the method of invention I requires the use of nucleic acid primers or probes and requires performing hybridization or amplification or nucleic acid sequencing reactions in order to achieve the objective of detecting variation in a GH1 nucleic acid. Invention

IV requires the use of proteins and involves the steps of sequencing proteins, performing ligand binding assays or Western blotting in order to achieve the objective of detecting a GH1 variant protein. Invention V requires the use of a GH1 nucleic acid and a pharmaceutical composition and involves the step of administer to a patient a medicant comprising a GH1 nucleic acid in order to achieve the objective of treating a patient.

Inventions II and III are patentably distinct in structure and physicochemical properties. Invention II is drawn to nucleic acids whereas invention III is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention III do not require the particular products of the nucleic acids of invention II since the proteins of invention III can be isolated from natural sources or chemically synthesized.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention II are not required to practice the method of invention IV.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for diagnostic methods.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention III can be used in a materially different process, such as for therapeutic uses.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the proteins of invention III are not required to practice the method of invention V.

3.

Sequence Election

In addition, inventions I detailed above each reads on patentably distinct inventions drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each invention. Applicant must further elect a single nucleic acid sequence selected from the group of sequences recited in claim 11.

It is noted that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

3. ***Election Requirement Applicable to All Groups***

In addition, Applicant is required to elect a single nucleotide or amino acid variation from the variants set forth in the claims. For example, if Applicants elect invention II, then Applicants must further elect a single variance in the GH1 nucleic acid sequence. Each of the variants set forth in the specification are considered to be distinct from one another, since each variation occurs at a distinct location, has a distinct identity and modifies the stated gene or protein in a distinct manner. For example, a polymorphism at position X of the GH1 gene, would not render a polymorphism at position Y of the GH1 gene obvious. Accordingly, in the absence of evidence to the contrary, each variance is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. It is noted that the claims that are drawn generically to a variant of GH1 nucleic acid or protein and generic methods of using and detecting GH1 variant nucleic acids will be examined for the entire scope, i.e. as including any variation in the GH1 nucleic acid or protein sequence. However, the claims

which recite specific variants, will be examined for only the elected nucleic acid or protein variant.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. In response to this Office action, Applicants must amend the specification and claims to include the appropriate sequence identifier next to each sequence recited, as required under 37 CFR §1.821(d). See for example, claim 11 and page 40 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER